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APPLICATION NO. 326	FILING DATE 11/15/99	FIRST NAMED INVENTOR ROCK	ATTORNEY DOCKET NO.
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HM22/1004

EXAMINER

HAMUD, F

ART UNIT	PAPER NUMBER
1647	5

DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

<b>Office Action Summary</b>	Application No. <b>09/419,328</b>	Applicant(s) <b>Alain H. ROOK</b>
	Examiner <b>Fozia Hamud</b>	Group Art Unit <b>1647</b>

Responsive to communication(s) filed on Dec 20, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-3 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-3 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

1. Claims 1-3 are pending and under consideration by the Examiner.

### ***Claim Rejections - 35 U.S.C. § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2a. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Haku et al, 11/97.

Haku et al disclose a composition comprising recombinant interleukin-12 (IL-12) and recombinant interleukin-2 (IL-2), and showed that the combination of IL-12 and IL-2 at a suboptimal or optimal concentrations augmented IFN- $\gamma$  production, (see abstract and column 2 of page 848).

Instant claim 3, is drawn to a composition comprising recombinant IL-12 and an adjunct therapeutic agent which stimulates IF- $\gamma$  production. Therefore, since Haku's reference discloses a composition comprising recombinant IL-12 and IL-2 and since Haku et al showed that this composition stimulates IF- $\gamma$  production, Haku et al clearly anticipates instant claim 3. With respect to the limitation that the claimed composition is for treatment of advanced cutaneous T cell lymphoma, this is an intended use of the claimed composition which adds no patentable weight to the said composition.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3a. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rook et al (1996) in view of Haku et al (November 1997).

Rook et al teach that there is a marked defect in IL-12 production by peripheral blood mononuclear cells (PBMCs) from patients with sezary syndrome (SzS, an advanced form of cutaneous T cell lymphoma) and that normal levels of IL-12 can be restored by exogenous recombinant IL-12, (page 315, second paragraph). Rook et al also teach that exogenous recombinant IL-12 enhanced depressed IFN- $\gamma$  production by PBMCs from SzS patients, and that *in vitro* culture of PBMC from SzS patients with recombinant IL-12 leads to reconstitution of normal IFN- $\gamma$  production and markedly enhances cell-mediated cytotoxicity, (page 316, last paragraph and figure 2). Rook et al teach that Th2 cytokines (IL-4 and IL-5) are detected in skin lesions of patients with cutaneous T-cell lymphoma, and that the excess IL-4 production by SzS PBMCs can be inhibited *in vitro* by IFN- $\gamma$ .

The teachings of Haku et al is set forth in paragraph 2a of this office action, however, neither Rook et al nor Haku et al teach a method for treatment of advanced cutaneous T cell lymphoma in a human by administering recombinant IL-12 (claim 1) and an adjunct therapeutic agent which stimulates IFN- $\gamma$  production.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made, to design a method of treating advanced cutaneous T cell lymphoma in a human by administering recombinant IL-12, because Rook et al teach that exogenous recombinant IL-12

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enhanced depressed IFN- $\gamma$  production by PBMCs from SzS patients and enhanced cell-mediated cytotoxicity, and that the excess IL-4 production by SzS PBMCs was inhibited in vitro by IFN- $\gamma$ . Furthermore, it would have been obvious to design a method of treating advanced cutaneous T cell lymphoma by administering recombinant IL-12 with adjunct therapeutic agent which stimulates IFN- $\gamma$  production, because Haku et al teach that recombinant IL-12 together with recombinant IL-2 at a suboptimal or optimal concentrations augmented IFN- $\gamma$  production, and Rook et al teach that augmenting IFN- $\gamma$  production favors the enhancement of anti-tumor mediated immune responses.

Thus one of ordinary skill in the art would have been motivated to design a method for treatment of advanced cutaneous T cell lymphoma in a human by administering to said human IL-12 and adjunct therapeutic agent which stimulates IFN- $\gamma$  production, because this is a debilitating disease characterized by decreased IL-12, IL-2 and IFN- $\gamma$ , and restoring normal levels of these cytokines would be expected to be beneficial to patients suffering from this disease.

### ***Conclusion***

6. No claim is allowed.

### ***Advisory Information+***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647

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September 29, 2000

CHRISTINE SAoud  
PATENT EXAMINER

*Christine Saoud*